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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,972	12/28/2000	Pramod K. Srivastava	8449-134	7769
20583	7590	03/13/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/750,972	SRIVASTAVA, PRAMOD K.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75,97,99-101,111,112,122,129 and 132 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75,97,99-101,111,122,129 and 132 is/are rejected.
- 7) ☒ Claim(s) 112 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/9/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Srivastava P.K.

The amendment filed 11/28/2003 is acknowledged and entered into the record.

Accordingly, claims 1-74,76-96,98,102-110,113-121,123-128,130-131, and 133-147 are canceled without prejudice or disclaimer.

Claims 75,97,99-101,111-112,122,129, and 132 are pending and examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The Information Disclosure Statement filed 7/9/2004 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained - 35 USC § 102

The rejection of claims 75,97,99-101,111,122,129, and 132 as being anticipated by Strickland *et al* (US Patent 6,156,311) as evidenced by Weiner *et al*, Singh (Gerontology 1997;43:79-94), and D'Andrea MR (Med. Hypotheses. 2005;64(3):458-463) under 35 USC § 102(e) is maintained for the reasons of record. Applicant argues the that claims of the instant invention are not anticipated by Strickland *et al*.

Specifically, applicant argues that Strickland *et al* do not teach nor disclose a method of treating an autoimmune disorder. Applicant further contends that the examiner has

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mischaracterized the term dense deposit disease as being equivalent to Alzheimer's disease (AD). Applicant supports this assertion by referencing the Merck Manual citing passages that characterize dense deposit disease as being a disease associated with immune complex deposits in the kidney. Applicant further argues that Alzheimer's disease is "not an autoimmune disorder" as defined in the specification or as being an art recognized autoimmune disorder. Applicant further indicates that the specification characterizes Alzheimer's disease as being an alternative to autoimmune disease (applicant points to page 7, lines 33-37 and page 13, lines 12-16). Applicant further argues that those of skill in the art would not have recognized "at the relevant time, i.e. the filing date of the instant application" that Alzheimer's disease was an autoimmune disease in view of the teachings of Weiner *et al.* Applicant further points to the Merck Manual for a definition of autoimmune diseases. Finally applicant concludes that Alzheimer's disease is not encompassed by the instant claims, based on the fact that the claims are drawn to treating autoimmune diseases, of which Alzheimer's is excluded. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). In the instant case, although Alzheimer's disease (AD) was not fully characterized as being an autoimmune disease at the time of the invention (see Singh Gerontology 1997;43:79-

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94), subsequent characterizations of the disease indicates that the disease is in fact an autoimmune disease (see D'Andrea MR Med. Hypotheses. 2005;64(3):458-463).

Specifically, Singh teaches 5 general characteristics of autoimmunity (see page 82, left column), among these include cell-mediated immunity to auto-antigens and the production of auto-antibodies *in vitro* and *in vivo*. Singh also indicates that cell-mediated immunity may play a role in the induction of autoimmunity (see page 80).

Singh specifically indicates that AD is a disease which may involve the CD8⁺ and CD4⁺ T-cell arm of the immunoregulatory network (see page 91). Finally, Singh concludes that autoimmune diseases in general are genetically determined and indicates that AD may not be any different (see page 91).

Moreover, others have recently indicated that Alzheimer's disease has characteristics associated with autoimmune disorders. Specifically, D'Andrea teaches that auto-antibodies have been detected in the serum, CSF and in amyloid plaques of patients with AD (see page 459) and have been found to be associated with autoimmunity-induced cell death (see abstract). Therefore, Alzheimer's disease, although not fully characterized as being an autoimmune disease at the time of the invention, has been associated or characterized as being a disorder involving autoimmunity.

Finally, references cited to show a universal fact need not be available as prior art before applicant's filing date. In re Wilson, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism. In the instant case, although some of the cited references (i.e. Weiner *et al* and

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D'Andrea) are post filing date references, the references are used to show that Alzheimer's disease is inherently an autoimmune diseases and is therefore a scientific truism. Irregardless of whether the disease was characterized as being an autoimmune disease post-filing, the method performed by Strickland *et al* (i.e. the administration of anti-CD91 antibody) would, as now claimed, treat an autoimmune diseases.

Therefore, the rejection of claims under 35 USC 102(e) as being anticipated by Strickland *et al* is maintained for the reasons of record.

Conclusion

Claim 112 is objected to as being dependent on a rejected claim. Consequently, no claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen, Examiner
Art Unit 1643
February 22, 2006


CHRISTOPHER YAEN
PATENT EXAMINER